K031615

510(k) SUMMARY

DENTSPLY

NAME & ADDRESS:

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JUL 2 1 2003

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: May 22, 2003

TRADE OR PROPRIETARY NAME: SLED CURING LIGHT SYSTEM

CLASSIFICATION NAME: visible light cure for polymerization

PREDICATE DEVICES:	Spectrum™ 800 Curing Unit	982318
	Nova Cordless Light	000393

DEVICE DESCRIPTION:

The SLED CURING LIGHT is a cordless battery-powered unit designed for curing VLC materials whose initiators are sensitive to light in the 450-475 nm wavelength region of the visible spectrum. The light is based on LED (light emitting diodes) technology for light generation.

The SLED CURING LIGHT SYSTEM includes:

- Handpiece with an LED and control electronics
- Tapered fiber-optic probe to deliver the light to a well-defined site
- Battery for sustained electronic power
- Base unit - charges battery
  - stores handpiece when not in use
- Transformer to supply wall power to the base unit
- Optional amber-colored eye shield

The SLED CURING LIGHT handpiece contains three switches: one trigger to turn the curing LED on and off and two mode switches to cycle the curing time and type through several different settings. The battery in the handpiece is contained in a user-serviceable compartment.

510(k) SUMMARY (cont'd.)

INTENDED USE:

Curing camphorquinone-based visible light cured (VLC) materials.

TECHNOLOGICAL CHARACTERISTICS:

The SLED CURING LIGHT SYSTEM is substantially equivalent to K982318 in intended use, appearance and design, including source placement, probe style, on-board radiometer, control circuit, handpiece style.

The SLED CURING LIGHT SYSTEM is substantially equivalent to K000393 in intended use, operation, including the range of light emitted, curing time, and cooling.

We believe the similarity of the SLED CURING LIGHT SYSTEM to the legally marketed predicate devices and the performance data provided support the safety and effectiveness of the SLED CURING LIGHT SYSTEM for the indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1 2003

Mr. P. Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International
570 West College Avenue
P.O. Box 872
17405- 0872 York, Pennsylvania

Re: K031615
Trade/Device Name: SLED CURING LIGHT SYSTEM
Regulation Number: 872. 6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBT
Dated: May 22, 2003
Received: May 27, 2003

Dear Mr. Lehn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Susan Runner, DDDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K031615

Device Name: SLED CURING LIGHT SYSTEM

Indications for Use:

Curing camphorquinone-based visible light cured (VLC) materials.

RS Betz DDS for Dr. K. Mulay
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K031615

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)